

### **REMARKS/ARGUMENTS**

Claims 1-47 are pending in this application. Claims 1 and 3-7 currently have been amended. Claim 2 is canceled. Claim 47 newly has been added.

#### **Finality of Office Action**

The Office action dated December 10, 2007 has been designated as "final." Item 11 of the Office action on page 9 states that "Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL."

However, Applicant's response (dated November 18, 2007) to the final Office action (dated September 18, 2007) did not contain any amendments. Applicant pointed out in that response that Nakayama (US 2006/0036311) was an improper reference under 35 USC § 102(e). In the present Office action, the Office noted that Nakayama is not a proper 35 USC § 102(e) reference (Page 2, Item 4).

Under the present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by the applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). MPEP § 706.07(a)

The Office has discovered and applied a new reference O'Brien et al. (US 2005/0060021) in the present Office action and has made it final. Such action was not necessitated by Applicant or Applicant's amendment of which there were none.

In view of the foregoing, Applicant submits that the finality of the Office action is improper and request its reconsideration and withdrawal.

### **35 U.S.C. § 102 Rejection**

Claims 1-10, 12, 14, 15, 17-19, 29, 30, 34-37, 39, 43, and 44 are rejected under 35 USC § 102(e) as being anticipated by O'Brien et al. (US 2005/0060021).

The Office believes O'Brien et al. disclose a stent comprising a scaffold from a third material, an intermediate fourth material, a porous surface comprising a first coating material having a plurality of discrete pores and a second composite material comprising a plurality of particles located within each of the pores and composed of a bioactive agent in combination with a bioerodable polymer material.

Applicant has amended claim 1 now to state that the claimed stent system requires:

“... a porous surface on the endolumenal stent  
comprising a first material and having a plurality of pores;  
and  
a second composite material that is different than the  
first material and that is located within each of the pores and  
comprising a bioerodable material in combination with a  
bioactive agent wherein the second composite material  
comprises a plurality of particles.”

A party asserting that a patent claim is anticipated under 35 USC 102 must demonstrate among other things, “identity of invention.” *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). For a prior art reference to anticipate in terms of 35 USC 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, (Fed. Cir. 1990).

O'Brien et al. do not show each and every element of the rejected claims as presently amended, namely claim 1 and all claims which depend on claim 1. O'Brien et al. therefore do not anticipate these claims. Presently amended claim 1 now includes the features of canceled claim 2 and reads "...wherein the second composite material comprises a plurality of particles." Contrary to the Office's assertion that a plurality of particles is disclosed, Applicant cannot find such a disclosure anywhere in O'Brien et al. O'Brien et al. **do not disclose a plurality of particles.** The Office's reference to ¶36 of O'Brien et al. to show the teaching of particles is improper because Figure 2C of O'Brien et al. does not show particles but is a view from the top or bottom of a tubular element. The diameters indicated refer to the diameter of the tube and not to any particle. Applicant refers to Fig. 2 of the present disclosure, specifically to item **40** which shows an example of the particles as now presently claimed in claim 1.

Independent claims 44, 45 and 46 already recite "...a plurality of composite **particles.**" O'Brien et al. do not teach this element of claims 44-46 and therefore do not anticipate the claim.

New added claim 47 recites "...wherein the particles comprise an outer diameter that is greater than about 1 micron and less than about 5 microns." Figure 2C depicts a view from the top or bottom of a tubular element. The diameter refers to the diameter of the tube and not to any particle. The diameter is also indicated to be less than 1 micron in O'Brien et al. The particles according to claim 47 have an outer diameter that is greater than about 1 micron and less than about 5 microns. Thus, the particles according to the present disclosure are not taught by O'Brien et al. and further would not be able to fit inside the tubular element as shown in Figure 2C of O'Brien et al. O'Brien et al. do not teach each and every element of claim 47 and therefore do not anticipate it.

Applicant further notes that various additional claims that depend from independent claim 1 remain in the present application. These dependent claims are either preserved in their original form or are also hereby amended to clarify certain

aspects captured by the particular claim(s). These claims variously provide further distinguishing features over the presently known art, including the O'Brien et al. disclosure cited in the present rejection. This is in particular the case with respect to the overall combinations of features claimed through dependency, which incorporate by reference the distinguishing features of claim 1 as noted above.

In addition, however, the further features and aspects noted in these dependent claims also provide additional separation from the disclosed art that Applicant submits are sufficient to render such claims allowable over and above the basis from respectively incorporated claim 1.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the Office's rejection of claims 1-10, 12, 14, 15, 17-19, 29, 30, 34-37, 39, 43, and 44 under 35 USC § 102.

### **35 U.S.C. § 103 Rejections**

Claims 11, 13, and 16 are rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claims 1 and 12, in view of Lye et al. (US 2004/0148015).

Regarding claims 11 and 16, the Office stated that although O'Brien et al. do not disclose that the first material is sintered or is inherently obvious, Lye et al. disclose a similar device including a stent with a porous surface and therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the first material included an inherently porous material, such as a sintered material, to simplify the manufacturing process by eliminating the step of forming the pores by anodization.

Applicant submits that O'Brien et al. in view of Lye et al. do not teach or suggest the elements of presently amended independent claim 1 and its dependent claims, and previously presented claims 44, 45, and 46. More specifically, the combination of

O'Brien et al. and Lye et al. do not teach or suggest the second composite material of the present endolumenal stent system comprising a **plurality of particles**.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 11, 13, and 16 under 35 USC § 103.

Claims 20-28, 31-33, 45, and 46 are rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. (US2005/0060021), as applied to claim 19, in view of Gertner et al. (US 2003/0060873).

The Office stated that although O'Brien et al. do not disclose that the electrochemically deposited material is an electrolessly electrochemically deposited material including a composite with a metal and a reducing agent of that metal, Gertner et al. disclose a similar device including a stent comprising a scaffold, a porous surface on the stent comprising a first material and a plurality of pores and a second material comprising a bioactive agent located within the pores using an alternate first material.

Applicant submit that O'Brien et al. in view of Gertner et al. do not teach or suggest the elements of presently amended independent claim 1 and its dependent claims, and previously presented claims 44, 45, and 46. More specifically, the combination of O'Brien et al. and Gertner et al. do not teach or suggest the second composite material of the present endolumenal stent system comprising a **plurality of particles**.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 20-28, 31-33, 45 and 46 under 35 USC § 103.

Claim 38 is rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 1, in view of Wang et al. (US 2007/0037739).

Regarding claim 38, the Office stated that although O'Brien et al. do not disclose the bioactive agent may comprise des-aspartate angiotensin 1, Wang et al. disclose

compounds useful in coating stents to treat restenosis including des-aspartate angiotensin 1 which has been shown to substantially inhibit smooth muscle cell proliferation and drastically reduce restenosis.

Applicant submits that O'Brien et al. in view of Wang et al. do not teach or suggest the elements of presently amended independent claim 1 and its dependent claims, and previously presented claims 44, 45, and 46. More specifically, the combination of O'Brien et al. and Wang et al. do not teach or suggest the second composite material of the present endolumenal stent system comprising a **plurality of particles**.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection of claim 38 under 35 USC § 103.

Claims 40-42 are rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 1.

Regarding claims 40-42, the Office stated that although O'Brien et al. do not disclose the ratio of bioactive material to the bioerodable material it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the second composite material was formed with a ratio of bioactive material to bioerodable material to be at least 0.5:1, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art.

Applicant submits that O'Brien et al. does not teach or suggest the elements of presently amended independent claim 1 and its dependent claims, and previously presented claims 44, 45, and 46. More specifically, O'Brien et al. does not teach or suggest the second composite material of the present endolumenal stent system comprising a **plurality of particles**.

New added claim 47 recites "...wherein the particles comprise an outer diameter that is greater than about 1 micron and less than about 5 microns." Figure 2C depicts a view from the top or bottom of a tubular element. The diameter refers to the diameter of the tube and not to any particle. The diameter is also indicated to be less than 1 micron in O'Brien et al. The particles according to claim 47 have an outer diameter that is greater than about 1 micron and less than about 5 microns. The particles according to the present disclosure are not taught by O'Brien et al. and further would not be able to fit inside the tubular element as shown in Figure 2C of O'Brien et al. O'Brien et al., by itself or in combination with any other reference cited by the Office, do not teach or suggest each and every element of claim 47.

In view of the foregoing, Applicant respectfully request withdrawal of the rejection of claims 40-42 under 35 USC § 103.

### **CONCLUSION**

Applicant respectfully requests a timely Notice of Allowance be issued in this application. Should any issues remain, the Examiner is invited to contact the undersigned. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment, or credit any overpayment, to Deposit Account No. 50-3207.

Respectfully submitted,

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